OCT 2 6 2012

510(k) Summary of Safety and Effectiveness

Identification of manufacturer

Company:	Philips Medical Systems Nederland B.V.
Address:	Veenpluis 4-6, 5684-PC, Best, the Netherlands
Registration number:	3003768277

Identification of U.S. designated agent

Company:	Philips Medical Systems
Address:	22100 Bothell Everett Highway Bothell, WA 98021-8431, U.S.A.
Registration number:	1217116

Identification of official correspondent

Name:	Frans Jacobs
Position:	Regulatory Affairs Manager
Telephone:	+31-40-27-99709
Date prepared:	June 6, 2012

Device identification

Trade name:	EchoNavigator
Device name:	EchoNavigator Release 1
Regulation description:	Picture archiving and communications system
Regulation number:	21CFR 892.2050
Class:	II
Product code:	90LLZ

Legally marketed devices

Trade names:	HeartNavigator Release 1
Manufacturer:	Philips
510(k) numbers:	K111245 - Jul 29, 2011
Trade names:	QLAB with FHN and VPQ plug-in
Manufacturer:	Philips
510(k) numbers:	K121223 – May 15, 2012

Device description

The **EchoNavigator Rel. 1** software medical device is a tool that assists the interventionalist and surgeon with image guidance during treatment of cardiovascular disease in which the procedure uses both live X-ray and live Echo guidance. The **EchoNavigator Rel. 1** device can be used with the currently marketed Philips EchoNavigator compatible Echo-probes, Echo units and interventional X-ray systems.

Indications for Use:

EchoNavigator supports the interventionalist and surgeon in treatments where both live X-ray and live Echo guidance are used. The targeted patient population consists of patients with cardiovascular diseases requiring such a treatment.

Technological characteristics

The **EchoNavigator Rel. 1** software medical device is executed on a PC based hardware platform.

Summary of testing

The **EchoNavigator Rel. 1** software medical device complies with international recognized standards as detailed in the premarket submission. Non-clinical verification and validation tests were performed with regards to the requirement specifications and risk management results, specifically including software verification and validation activities. The results of these tests demonstrate that **EchoNavigator Rel. 1** met the acceptance criteria.

Conclusion:

The **EchoNavigator Rel. 1** software medical device is substantially equivalent to the currently marketed and predicate Philips' HeartNavigator and QLAB with FHN and VPQ plug-in software medical devices based on the similar indications for use, device functionality and technology (hardware and software).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

OCT 2 6 2012

Mr. Frans Jacobs
RegulatoryAffairs Manager
Philips Medical Systems Nederland B.V.
Veenpluis 4-6
Best, 5684 PC
THE NETHERLANDS

Re: K121781
Trade/Device Name: EcoNavigator
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 16, 2012
Received: August 31, 2012

Dear Mr. Jacobs:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

EchoNavigator supports the interventionalist and surgeon in treatments where both live X-ray and live Echo guidance are used. The targeted patient population consists of patients with cardiovascular diseases requiring such a treatment.

Prescription Use __yes_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __No___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K121781